REMARKS

Claims 27 has been amended to correct a typographical error. Claims 27-28 are pending in the present application.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

I. Sequence Compliance

The Office Action requested a computer readable form (CRF) and paper copy of the Sequence Listing with a statement that the CRF and paper copy of the Sequence Listing are the same. Applicant submits a paper copy of the Sequence Listing with a statement that the CRF and the paper copy of the Sequence Listing are the same.

II. The Rejection of Claims 27-28 under 35 U.S.C. § 112, First Paragraph

Claims 27-28 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for reasons of record in the Office Action filed April 24, 2002, and restated below:

> Since the specific *Fusarium venenatum* cells deposited at ATCC 20334 are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. The invention does not recite use of any cells but instead specifically claims *Fusarium venenatum* cells deposited at ATCC with deposit #20334. The *Fusarium venenatum* cells deposited at ATCC under #20334 are commercially available, however, commercial availability is not necessarily evidence that the public will have access to the material for the life of a patent (see MPEP 2404.01) (emphasis added). The *Fusarium venenatum* of the invention were apparently deposited by others, their availability in an unrestricted form for the life of a patent issued on the instant application cannot be ensured. Applicants must therefore deposit the specific *Fusarium venenatum* recited in the claims and thus satisfy the deposit requirement under 37 CFR 1.801-1.809.

This rejection is respectfully traversed.

The Office Action of April 24, 2002, noted that CPR 1.802(b) states that public access during the term of the patent may affect the enforceability of the patent, and that in order to ensure that the cells are available for the life of the patent, the applicant must satisfy the deposit requirement under 37 CPR 801-1.809. However, the Office Action failed to note that 37 C.F.R. 1.802(b) further states that "[b]iological material need not be deposited, *inter alia*, if it is known and readily available to the public...."

Applicants in the Amendment of October 24, 2002, enclosed a copy of page 178 of the ATCC catalogue for 1991 which lists *Fusarium* ATCC 20334. Also attached were pages from ATCC's website (www.atc.org) that disclose the strain is commercially available and may be purchased. Clearly, these publications establish that this strain was known prior to Applicants' filing date.

Applicants in the Amendment of October 24, 2002, pointed out that when the Patent Office adopted the rules on the deposit of biological materials, it issued comments on interpreting and applying the rules. See 54 FR 34880. The comments regarding the terms "known and readily available" in 37 C.F.R. 1.802(b) are set forth at page 23 of 54 FR 34880 as follows:

> Even where access to biological material is required to satisfy these statutory requirements, a deposit may not be necessary if access sufficient to satisfy these requirements is otherwise available.
>
> For example, applicant could show that the biological material is known and readily available to the public. The concepts of "known and readily available" are considered to reflect a level of public accessibility to a necessary component of an invention disclosure that is consistent with an ability to make and use the invention. To avoid the need for a deposit on this basis, the biological material must be both known and readily available - neither concept alone is sufficient....
>
> By showing that a biological material is known and readily available or by making a deposit in accordance with these rules, applicant does not guarantee that such biological material will be available forever. Public access during the term of the patent may affect the enforceability of the patent. Although there is a public interest in the availability of the deposited material during and after the period of enforceability of the patent, the examiner need not be unduly concerned about continued access to the public. Unless there is a reasonable basis to believe that the biological material will cease to be available during the life of the patent, the examiner should accept current availability as satisfying the requirement. The incentives provided by the patent system should not be constrained by the mere possibility that a disclosure that was once enabling would become non-enabling over a period of time through no fault of the patentee. *In re Metcalfe*, 410 F.2d 1378, 161 USPQ 789 (CCPA 1969) (emphasis added).

The above-noted comments on interpreting and applying the deposit rules clearly provide that although there is a public interest in the availability of the deposited material during and after the period of enforceability of the patent, the examiner need not be unduly concerned about continued access to the public, unless there is a reasonable basis to believe that the biological material will cease to be available during the life of the patent, the examiner should accept current availability as satisfying the requirement. The Office Action states: "The *Fusarium venenatum* cells deposited at ATCC under #20334 are commercially

available, however, commercial availability is not necessarily evidence that the public will have access to the material for the life of a patent (see MPEP 2404.01) (emphasis added)." However, the Office Action fails to note that MPEP 2404.01 further states: "The Office will accept commercial availability as evidence that a biological material is known and readily available only when evidence is clear and convincing that the public has access to the material." The MPEP follows the comments on interpreting and applying the rules under 54 FR 34880.

Applicants enclosed in the Amendment of October 24, 2002 a letter from Elizabeth Kerrigan of the American Type Culture Collection dated July 10, 2003, which confirms that *Fusarium* ATCC 20334 is preserved in the open collection of the ATCC and is "known and readily available". The Kerrigan letter provides clear and convincing evidence that the public has access to the material.

Applicants submit that the microorganism recited in the claims is "known and readily available" and, therefore, Applicants do not have to provide the assurances requested in the Office Action.

For the foregoing reason, Applicants submit that this rejection under 35 U.S.C. § 112 has been overcome and respectfully request withdrawal of the rejection.

III. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

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